IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Radunsky, et al. Attorney Docket No.: 3154/103

App. No.: 10/796,882 Art Unit: 1797

Filing Date: 03/08/2004 Examiner: Drodge, Joseph W.

For: Method and System for Colloid Exchange Therapy

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Summary of Interview

Dear Sir:

The Applicants provide this summary of the telephonic interview with Examiner Drodge of December 3, 2008.

- 1) Exhibits. No exhibits were shown or discussed.
- 2) Identification of claims discussed. Claim 17 was discussed.
- 3) Identification of prior art discussed. Nose was discussed.
- 4) <u>Identification of principal proposed amendments discussed</u>. An Examiner's Amendment was agreed upon as outlined in the listing of claims below.
- 5) Brief identification of general thrust of principal arguments presented to the examiner.

The wording of the Examiner's amendment was discussed.

- 6) General Indication of any other pertinent matters discussed. None.
- General results or outcome. Agreement was reached regarding the Examiner's Amendment.

Listing of Claims

1-16. (cancelled)

17. (currently amended) An extracorporeal blood filtration circuit for treating a patient's blood to remove target molecules and target complex molecules, the circuit comprising:

a line adapted to remove and to return a portion of the patient's blood <u>without being</u> sieved;

a blood filter operably coupled with the line so as to allow the portion of the patient's blood to flow therethrough, the blood filter operable to form a stream of filtered blood and a stream of ultrafiltrate with an ultrafiltration rate of between approximately two liters per hour and twenty liters per hour, the blood filter having a nominal molecular weight cutoff of greater than 150,000 Daltons and less than 1,000,000 Daltons so as to sieve more than a nominal amount of the target molecules and the target complex molecules from the portion of the patient's blood and to avoid removal of significant amounts of immunoglobulins from the portion of the patient's blood:

a source for infusing a replacement fluid into the blood circuit, the source including replacement fluid comprising clean target receptor molecules in sufficient amount so as to provide sufficient clean target receptor molecules to sequester inflammatory mediators and toxins from the patient's tissue and to replace the target receptor molecules sieved from the portion of the patient's blood by the blood filter, and sufficient albumin to maintain adequate plasma oncotic pressure with ultrafiltration rates between approximately two liters per hour and twenty liters per hour in a sufficient concentration to adequately replenish ongoing losses.

18. (previously presented) The extracorporeal blood circuit of Claim 17, wherein the replacement fluid comprises a concentration of albumin in the fluid greater than approximately 0.5 grams per one hundred milliliters.

19. (previously presented) The extracorporeal blood circuit of Claim 17 wherein the replacement

fluid comprises a concentration of albumin in the fluid less than approximately twenty grams per one hundred milliliters.

- 20. (canceled)
- 21. (canceled)
- 22. (previously presented) The extracorporeal blood circuit of Claim 17 wherein the blood filter comprises a nominal molecular weight cut off less than 500,000 Daltons.
- 23. (previously presented) The extracorporeal blood circuit of Claim 17, wherein the clean target receptor molecules are albumin molecules.
- 24. (previously presented) A method for removing toxic substances from the blood of a patient, the method comprising:

withdrawing blood from the patient;

delivering the blood to a hemofilter having pores, the hemofilter characterized by a molecular weight cutoff of greater than 150,000 Daltons and less than 1,000,000 Daltons so as to create a return stream having retained molecules that did not pass through the pores and an ultrafiltrate characterized by having molecules that passed through the pores;

removing at least a portion of the ultrafiltrate, so as to remove toxic substances contained in the ultrafiltrate from the blood;

returning the return stream to the patient; and
providing a fluid, containing clean target receptor molecules, to the patient.

- 25. (previously presented) A method according to claim 24 wherein the molecular weight cutoff is a nominal molecular weight cutoff.
- 26. A method according to claim 24 wherein the target recentor molecules comprise albumin.

- 27. (previously presented) A method according to claim 24 wherein the target receptor molecules consist of albumin.
- 28. (previously presented) A method according to claim 24 wherein the target receptor molecules consist of albumin and another substance.
- 29. (previously presented) A method according to claim 28 wherein the other substance is a specific target receptor.
- 30. (previously presented) A method according to claim 24 wherein providing the fluid includes delivering albumin in an amount sufficient to maintain adequate oncotic pressure.
- (previously presented) A method according to claim 24 further comprising removing all
 of the ultrafiltrate.
- 32. (previously presented) A method according to claim 24 further comprising cleaning and returning at least a portion of the ultrafiltrate.
- 33. (previously presented) A method according to claim 32 wherein cleaning includes using an adsorbent material.
- 34. (previously presented) A method according to claim 24, wherein removing includes removing a predetermined amount of ultrafiltrate based on one of the body size of the patient, the time of therapy, and the rate of flow of blood to the hemofilter.
- 35. (previously presented) A method according to claim 24 wherein removing includes adjusting the rate of ultrafiltrate removal by altering the rate of delivering blood to the hemofilter.
- 36. (previously presented) A method according to claim 24 wherein providing the fluid

includes delivering the fluid to the patient via a line.

37. (previously presented) A method according to claim 36 wherein providing the fluid includes providing it concurrently with removing at least a portion of the ultrafiltrate.

38. (previously presented) A method according to claim 24 wherein the toxic substances are pro-inflammatory mediators.

39. (previously presented) A method according to claim 38 further comprising practicing the withdrawing, delivering, removing, returning and providing so as to remove a sufficient amount of inflammatory mediators so as to effect an anti-inflammatory response from the patient.

40. (previously presented) A method according to claim 24, further comprising infusing the fluid directly into the patient.

41. (previously presented) A method according to claim 24, further comprising infusing the fluid into a blood circuit associated with the hemofilter.

42. (previously presented) A method according to claim 24, further comprising practicing the withdrawing, delivering, removing, returning and providing over a duration of between 4-24 hours.

43. (previously presented) A method according to claim 24, further comprising using an ultrafiltration rate of between 2 and 20 liters per hour.

44. (previously presented) A method according to claim 24, further comprising using an ultrafiltration rate of between 6 and 12 liters per hour.

Applicant submits that all claims pending in the application are allowable over the art of record. Early notice to that effect is respectfully solicited. Reconsideration of the application and issuance of a notice of allowance are respectfully requested. It is believed that no extension of time is required, but Applicant hereby petitions for and request that any extension or other fee required for timely consideration of this application be applied and charged to Deposit Account No. 19-4972. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Respectfully submitted,

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